General

Guideline Title

Evidence-based guideline update: intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society.

Bibliographic Source(s)

Nuwer MR, Emerson RG, Galloway G, Legatt AD, Lopez J, Minahan R, Yamada T, Goodin DS, Armon C, Chaudhry V, Gronseth GS, Harden CL. Evidence-based guideline update: intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and [trunc]. Neurology. 2012 Feb 21;78(8):585-9. [26 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

Conclusion

Intraoperative monitoring (IOM) is established as effective to predict an increased risk of the adverse outcomes of paraparesis, paraplegia, and quadriplegia in spinal surgery (4 Class I and 7 Class II studies).

Recommendation

Surgeons and other members of the operating team should be alerted to the increased risk of severe adverse neurologic outcomes in patients with important IOM changes (Level A).

Clinical Context

In practice, after being alerted to IOM changes, the operating team intervenes to attempt to reduce the risk of adverse neurologic outcomes. No studies in humans have directly measured the efficacy of such interventions. However, multiple controlled studies in animals have demonstrated that intervening after IOM alerts (as opposed to not intervening) reduces the risk of permanent neurologic injury. On this basis, it seems reasonable to

assume that such interventions might improve outcomes in humans as well. It is unlikely that controlled human studies designed to determine the efficacy of post-IOM alert interventions will ever be performed.

This analysis did not compare motor-evoked potential (MEP) with sensory-evoked potential (SEP). The 2 techniques differ slightly. MEP more directly monitors the motor pathway itself. One technique may change while the other remains stable, or one may change earlier than the other. MEP requires more restrictive anesthesia requirements, causes patient movement, and has less-clear criteria for raising an alarm. SEP can localize an injury or site of ischemia more exactly. The transcranial electrical MEPs (tceMEPs) are often used intermittently because of movements that occur with the stimulus. Sometimes one technique can be accomplished throughout a case, whereas the other techniques cannot. As a result, it may be most appropriate for the surgeon, anesthesiologist, and neurophysiologic monitoring team to choose which techniques are most appropriate for an individual patient. Conducting both techniques together is a reasonable choice for many patients. Neither technique can predict the onset of paraplegia that is delayed until hours or days after the end of surgery. Neither technique should be considered to have perfect predictive ability when no evoked potential change is seen; rare false-negative monitoring has occurred.

The studies reported in the guideline varied somewhat in the criteria used to raise alerts. The specific criteria used are reported in table e-1 of the original guideline document.

These IOM studies involved a knowledgeable professional clinical neurophysiologist supervisor. These studies support performance of IOM when conducted under the supervision of a clinical neurophysiologist experienced with IOM. IOM conducted by technicians alone or by an automated device is not supported by the studies reported here because these studies did not use that practice model and because there is a lack of identified well-designed published outcomes studies demonstrating efficacy with those practice models.

Definitions:

Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Classification of Evidence for Diagnostic Accuracy

Class I: A cohort study with prospective data collection of a broad spectrum of persons with the suspected condition, using an acceptable reference standard for case definition. The diagnostic test is objective or performed and interpreted without knowledge of the patient's clinical status. Study results allow calculation of measures of diagnostic accuracy.

Class II: A case control study of a broad spectrum of persons with the condition established by an acceptable reference standard compared to a broad spectrum of controls or a cohort study where a broad spectrum of persons with the suspected condition where the data was collected retrospectively. The diagnostic test is objective or performed and interpreted without knowledge of disease status. Study results allow calculation of measures of diagnostic accuracy.

Class III: A case control study or cohort study where either persons with the condition or controls are of a narrow spectrum. The condition is established by an acceptable reference standard. The reference standard and diagnostic test are objective or performed and interpreted by different observers. Study results allow calculation of measures of diagnostic accuracy.

Class IV: Studies not meeting Class I, II or III criteria, including consensus, expert opinion or a case report.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Conditions requiring spinal surgery

Guideline Category

Evaluation

Risk Assessment

Technology Assessment

Clinical Specialty

Anesthesiology

Neurological Surgery

Neurology

Orthopedic Surgery

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Hospitals

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate whether spinal cord intraoperative monitoring (IOM) with somatosensory and transcranial electrical motor evoked potentials (EPs) predicts adverse surgical outcomes

Target Population

Patients undergoing spinal surgery or certain surgeries of the aorta

Interventions and Practices Considered

Spinal cord intraoperative monitoring (IOM) with somatosensory and transcranial electrical motor evoked potentials

Major Outcomes Considered

Severe adverse neurologic surgical outcomes:

- Paraparesis
- Paraplegia
- Quadriplegia

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A research librarian performed literature searches of the MEDLINE and EMBASE databases using the following keywords: monitoring, intraoperative, evoked potentials, paralysis, and intraoperative complications. Additional articles were found from among the references cited in the reports reviewed. Each article was reviewed independently by at least 2 panel members. Appendix e-3 of the original guideline document presents the complete MEDLINE search strategy, and appendix e-4 presents the complete EMBASE search strategy.

The panel elected to focus on the 2 most common current spinal cord intraoperative monitoring (IOM) techniques. The somatosensory evoked potential (SEP) technique evaluated was ankle-wrist stimulation with neck-scalp recording. The motor evoked potential (MEP) technique evaluated was transcranial electrical MEP with muscle recording.

Minimum size for study inclusion was 100 patients for orthopedic procedures and 20 patients for neurosurgical or cardiothoracic procedures. Different numbers were used because the rates of adverse neurologic outcomes are lower for orthopedic spine procedures compared with those for neurosurgical and cardiothoracic procedures.

A study was included if it represented a consecutive series of a representative group of patients, preferably prospective; if the IOM followed a protocol established in advance; if the IOM changes were identified in real time, before outcomes were known; and if the clinical outcomes of interest (paraparesis, paraplegia, and quadriplegia) were clearly reported.

Number of Source Documents

12

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence for Diagnostic Accuracy

Class I: A cohort study with prospective data collection of a broad spectrum of persons with the suspected condition, using an acceptable reference standard for case definition. The diagnostic test is objective or performed and interpreted without knowledge of the patient's clinical status. Study results allow calculation of measures of diagnostic accuracy.

Class II: A case control study of a broad spectrum of persons with the condition established by an acceptable reference standard compared to a broad spectrum of controls or a cohort study where a broad spectrum of persons with the suspected condition where the data was collected retrospectively. The diagnostic test is objective or performed and interpreted without knowledge of disease status. Study results allow calculation of measures of diagnostic accuracy.

Class III: A case control study or cohort study where either persons with the condition or controls are of a narrow spectrum. The condition is

established by an acceptable reference standard. The reference standard and diagnostic test are objective or performed and interpreted by different observers. Study results allow calculation of measures of diagnostic accuracy.

Class IV: Studies not meeting Class I, II or III criteria, including consensus, expert opinion or a case report.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Reports were reviewed and scored independently by all content expert panelists. Those panelists discussed and resolved by consensus the methodology, results, relevance, and conclusions for a few reports for which there was initial panel discrepancy.

Next, these articles were rated using the American Academy of Neurology (AAN) 4-tiered (Class I–Class IV) classification of evidence scheme for rating diagnostic studies (see the "Rating Scheme for the Strength of the Evidence" field), and conclusions and recommendations were linked to the strength of the evidence (see the "Rating Scheme for the Strength of the Recommendations" field). All articles that were rated Class I or Class II are listed in table e-1 of the original guideline document.

The primary data evaluated were the results from a comparison of the group without evoked potential (EP) changes with the group with EP changes in both the number of cases with new postoperative paraparesis, paraplegia, and quadriplegia and the number without these conditions. Descriptive statistics and the Fisher exact test were used for statistical analysis.

The search identified an initial set of 604 reports. Of those, 40 articles met the inclusion criteria, but 28 were subsequently excluded because they contained Class III or IV data; did not address the outcomes of paraparesis, paraplegia, or quadriplegia; primarily assessed nerve roots instead of the spinal cord; or substantially relied on techniques beyond the scope of this guideline. Twelve studies provide evidence to assess the role of intraoperative monitoring (IOM) in the prediction of adverse outcomes (table e-1), 4 of which were Class I.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Seven physician clinical neurophysiologists were appointed to write this guideline because of their expertise in spinal intraoperative monitoring (IOM). The panel members were appointed jointly by the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) and the American Clinical Neurophysiology Society (ACNS). Five additional panel members served as methodology experts.

Conclusion and recommendations were linked to the strength of the evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least three committees of the American Academy of Neurology (AAN) and American Clinical Neurophysiology Society (ACNS), a network of neurologists, *Neurology* peer reviewers, and representatives from related fields.

The guideline was approved by the AAN Therapeutics and Technology Assessment Subcommittee on February 19, 2011; by the AAN Practice Committee on May 19, 2011; by the AAN Board of Directors on October 14, 2011; and by the ACNS Council on June 11, 2011.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Reduced adverse surgical outcomes through spinal cord intraoperative monitoring (IOM)

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

This statement is provided as an educational service of the American Academy of Neurology (AAN) and American Clinical Neurophysiology Society (ACNS). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods for care of a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodology. The AAN and ACNS recognize that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all circumstances involved. The clinical context section is made available to place the evidence-based guideline into perspective with current practice habits and challenges. No formal practice recommendation should be inferred.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Nuwer MR, Emerson RG, Galloway G, Legatt AD, Lopez J, Minahan R, Yamada T, Goodin DS, Armon C, Chaudhry V, Gronseth GS, Harden CL. Evidence-based guideline update: intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and [trunc]. Neurology. 2012 Feb 21;78(8):585-9. [26 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Feb 21

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

American Clinical Neurophysiology Society - Professional Association

Source(s) of Funding

This evidence-based guideline was funded by the American Academy of Neurology and the American Clinical Neurophysiology Society. No author received honoraria or financial support to develop this document.

Guideline Committee

Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society

Composition of Group That Authored the Guideline

Guideline Authors: M.R. Nuwer, MD, PhD, FAAN; R.G. Emerson, MD, FAAN; G. Galloway, MD, FAAN; A.D. Legatt, MD, PhD, FAAN; J. Lopez, MD; R. Minahan, MD; T. Yamada, MD; D.S. Goodin, MD; C. Armon, MD, MHS, FAAN; V. Chaudhry, MD, FAAN; G.S. Gronseth, MD, FAAN; C.L. Harden, MD

Therapeutics and Technology Assessment Subcommittee Members 2009–2011: Janis M. Miyasaki, MD, MEd, FAAN (*Co-Chair*); Cynthia L. Harden, MD (*Co-Chair*); Richard M. Camicioli, MD; Terry D. Fife, MD, FAAN; Jonathan Hosey, MD, FAAN (*Ex-Officio*); Cheryl Jaigobin, MD; Barbara S. Koppel, MD, FAAN; Jason Lazarou, MD; Alexander Rae-Grant, MD; William H. Theodore, MD, FAAN

Financial Disclosures/Conflicts of Interest

Conflict of Interest

The American Academy of Neurology (AAN) and American Clinical Neurophysiology Society (ACNS) are committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN and ACNS keep separate those who have a financial stake in the success or failure of the products appraised in the CPG and the developers of the guidelines. Conflicts of interest forms were obtained from all authors and reviewed by an oversight committee prior to project inception. AAN and ACNS limit the participation of authors with substantial conflicts of interest. They forbid commercial participation in, or funding of, guidelines projects. Drafts of the guideline have been reviewed by at least three committees of the AAN and ACNS, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com.

Disclosures

Dr. Nuwer estimates that 20% of his clinical effort is spent on intraoperative spinal cord monitoring; serves on a scientific advisory board for Corticare; serves on editorial advisory boards for *Clinical Neurophysiology, Journal of Clinical Neurophysiology, Practical Neurology*, and *Medical Economics*; receives publishing royalties for *Intraoperative Neurophysiologic Monitoring* (Cambridge University Press, 2010); serves as a consultant for Mattel; serves as Local Medical Director for SleepMed-Digitrace; receives research support from Bristol-Myers Squibb; holds stock in Corticare; and has provided depositions and expert testimony in medico-legal cases. Dr. Emerson has filed patents re: Dynamic adjustable spatial granularity for EEG display and systems and methods for measuring brain activity; serves as a consultant for Persyst Development Corporation; estimates that 85% of his clinical effort is spent on intraoperative monitoring; and receives research support from Cyberkinetics Neurotechnology Systems Inc., the NIH, NYS SCIRB, and the Epilepsy Foundation. Dr. Galloway estimates that 60% of her clinical effort is spent on intraoperative monitoring. Dr. Legatt serves on the editorial board of the *Journal of Clinical Neurophysiology*; holds equity in Entremed, Pfizer Inc, Teva Pharmaceutical Industries Ltd., GlaxoSmithKline, Johnson & Johnson, Schering-Plough Corp., GE Healthcare, and Proctor & Gamble; estimates that 65% of his clinical effort is spent on intraoperative monitoring; and has provided expert testimony in medico-legal cases. Dr. Lopez has received funding for travel from Cadwell Laboratories, Inc.; receives publishing royalties for *Intraoperative Neurophysiologic Monitoring* (Cambridge University Press, 2010); estimates that 60% of his clinical effort is spent on intraoperative monitoring;

and has provided expert testimony in medico-legal cases. Dr. Minahan estimates that 60% of his clinical effort is spent on intraoperative monitoring and has provided expert testimony in medico-legal cases. Dr. Yamada estimates that 10% of his clinical effort is spent on intraoperative monitoring; serves on the editorial board of the *Journal of Clinical Neurophysiology*; and receives publishing royalties for *Practical Guide for Clinical Neurophysiologic Testing: EEG* (Wolters Kluwer/Lippincott Williams & Wilkins, 2010) and *Practical Guide for Clinical Neurophysiologic Testing: EP, LTM, IOM, PSFG and NCS* (Wolters Kluwer/Lippincott Williams & Wilkins, 2011). Dr. Goodin has served on scientific advisory boards for Bayer Schering Pharma and Merck Serono; has received funding for travel and honoraria for speaking and consulting from Bayer Schering Pharma, Teva Pharmaceutical Industries Ltd., Novartis, and Merck Serono; has received speaker honoraria from Bayer Schering Pharma; has received research support from Bayer Schering Pharma and Novartis; and has served as an expert witness in medico-legal cases; holds equity interest in Teva Pharmaceutical Industries Ltd. and Biogen Idec. Dr. Armon has served on a scientific advisory board for Avanir Pharmaceuticals; serves on the editorial boards of *Neurology*® and *emedicine Neurology*; has received honoraria from Medscape Today; receives publishing royalties from emedicine.com for updating electronic chapters and from UpToDate; has received research support from Avanir Pharmaceuticals, Schwartz Biomedical, LLC, the NIH, and the Swiss PFO-Consortium; and has served as an expert witness in medico-legal cases. Dr. Chaudhry serves on the editorial board of *Neurologist*; is an inventor on patent(s) re: Total Neuropathy Score (TNS)—a score for evaluating peripheral neuropathies, for which he receives technology royalties from Abbott, Johnson & Johnson, and sanofiaventis; receives publishing royalties for *Harrison's Principles of Internal Medicine, 17th ed*, (McGraw Hill Companies, Inc., 2008); estimates that 40% of his clinical effort is spent on nerve conduction studies; has given expert testimony for the Department of Health and Human Services Vaccine Injury Compensation program; and receives research support from the Neuropathy Association and Nutricia. Dr. Gronseth serves as an editorial advisory board member of *Neurology Now*; serves on a speakers' bureau for Boehringer Ingelheim; and receives honoraria from Boehringer Ingelheim and the American Academy of Neurology. Dr. Harden serves on a scientific advisory board for Upsher-Smith Laboratories, Inc.; serves on speakers' bureaus for and has received speaker honoraria from Glaxo-SmithKline, UCB, and Lundbeck, Inc.; serves on the editorial boards of *Epilepsy Currents* and *Epilepsy Research*; receives publishing royalties from UpToDate, Inc.; and receives research support from Forest Laboratories, Inc., the Epilepsy Foundation, and the Milken Family Foundation.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site .

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

Availability of Companion Documents

The following are available:

- Evidence-based guideline update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials. Data supplement (e-appendices, e-tables). Available from the American Academy of Neurology (AAN) Web site .
- Update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials. AAN summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology. 2012. 2 p. Available in Portable Document Format (PDF) from the AAN Web site .
- Update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials. Case presentation. St. Paul (MN): American Academy of Neurology. 2012. 3 p. Available in PDF from the AAN Web site .
- Update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials. Slide presentation. St. Paul (MN): American Academy of Neurology. 2012. Available from the AAN Web site .
- Principles of coding for intraoperative neurophysiologic monitoring (IOM) and testing. American Academy of Neurology. Model medical policy. Available from the AAN Web site .
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the American Academy of Neurology (AAN) Web site .

Patient Resources

The following is available:

- Monitoring the spinal cord during surgery. AAN summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology. 2012. 2 p. Available in Portable Document Format (PDF) from the American Academy of Neurology (AAN) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on June 26, 2012.

Copyright Statement

Disclaimer

NGC Disclaimer